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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/435,274 11/05/99 CITOVSKY V 001.00301

HM22/0813

SUSAN J BRAMAN ESQ
BRAMAN & ROGALSKYJ LLP
P O BOX 352
CANANDAIGUA NY 14424-0352

EXAMINER

DAVIS, K

ART UNIT

PAPER NUMBER

1636

DATE MAILED: 08/13/01

Pl ase find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/435,274

Applicant(s)

CITOVSKY ET AL.

Examiner

Katharine F. Davis

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 July 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-78 is/are pending in the application.
- 4a) Of the above claim(s) 38-78 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9. 6) ☒ Other: *Notice To Comply*.

Art Unit: 1636

DETAILED ACTION

This Office Action is in response to the application filed on November 5, 1999 and to the Response to Election/Restriction Requirement filed on July 9, 2001. Claims 1-78 are pending in the instant application.

Election/Restrictions

Applicant's election of the subject matter of Group I (claims 1-37) in Paper No. 14, filed July 9, 2001 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election **without traverse** (MPEP § 818.03(a)).

Claims 38-78 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to a non-elected invention. Election was made **without** traverse in Paper No. 14, filed July 9, 2001.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Art Unit: 1636

Specification

The STIC made the following correction to the Sequence Listing filed on March 29, 2001: inserted additional header <223> in order that information could be read correctly by the computer program.

The specification contains nucleotide and/or amino acid sequences that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence and/or Amino Acid Sequence Disclosures. The sequences disclosed in Figure 17 must be labeled with a SEQ ID NO. This objection may be overcome by addition of the SEQ ID numbers to the Brief Description of Figure 17 in the specification. Additionally, it is unclear if these sequences are included in the Sequence Listing as originally filed. Applicant must provide a substitute paper copy and a substitute computer readable copy of the Sequence Listing (**only if the above-referenced sequences are not included in the originally filed Sequence Listing**) and a statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 CFR 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d). A full response to this Office action must include a complete response to the requirement for a new Sequence Listing.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7, 17 and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 (also claims 17 and 25) concludes with the phrase "...wherein the DNA binding domain is a LexA protein." The phrase is indefinite as it is unclear what is actually encompassed by the phrase. For example, does the fusion protein construct comprise the entire LexA nucleic acid sequence or just a portion of the sequence?

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-37 are rejected under 35 U.S.C. 102(a) as being anticipated by Ueki *et al.* (PCT document WO 98/49284, published on November 5, 1998). Ueki *et al.* disclose a method of determining the presence of a nuclear localization signal in a protein of interest, the method comprising: (1) selecting a host cell (eukaryotic and/or yeast) wherein the host cell expresses a

Art Unit: 1636

reporter gene (lacZ or a selection marker; for example His3); (2) constructing a chimeric nucleic acid encoding a fusion protein (transcription factor elements fused to a protein of interest) which is defective (transcription factor elements) in nuclear transportability said chimeric nucleic acid comprising a DNA binding domain (LexA) , an activation domain (Gal4) and a protein to be tested for the ability to be transported to the nucleus; and (3) introducing the chimeric nucleic acid into the host cell and determining expression of the reporter gene (see abstract and Figures). The chimeric nucleic acid of Ueki *et al.* also comprises a promoter (ADH1) to control expression of the fusion protein. The instant claims read on the methods, vectors and recombinant cells of Ueki *et al.*

Ueki *et al.* also disclose a nucleic acid encoding a DNA-binding domain of LexA. The LexA nucleic acid sequence of Ueki *et al.* is part of a disabled transcription factor which lacks the ability to transport nucleic acid (see Sequence Description, Geneseq database entry, AAV70967). The LexA nucleic acid sequence of Ueki *et al.* is nearly identical to that of the LexA sequence of the instant invention with only 3 mismatches over 608 bases. This is well within the rate of sequencing error. Additionally, Ueki *et al.* disclose the amino acid sequence of LexA (see Sequence Description, Geneseq database entry, AAW85001). The LexA amino acid sequence of Ueki *et al.* is nearly identical to that of the LexA sequence of the instant invention with only 1 mismatch over 202 bases. This is also well within the rate of sequencing error. Therefore, absent evidence to the contrary, the LexA gene (and corresponding protein) appears to be the same gene (and protein) as the LexA gene (and corresponding protein) claimed in the instant invention.

Art Unit: 1636

Conclusion

Claims 1-37 are rejected. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Katharine F. Davis whose telephone number is (703) 605-1195 with direct desktop RightFax (703) 746-5199. The examiner can normally be reached on Monday-Friday (8:30am-5:00pm). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Schwartzman can be reached on (703) 308-7307. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 305-1935 for After Final communications. Any inquiry concerning the formalities of this application should be directed to Patent Analyst Dianiece Jacobs whose telephone number is (703) 305-3388. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Katharine F. Davis
August 13, 2001



SEAN MCGARRY
PRIMARY EXAMINER